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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,686	07/25/2003	Seishi Kato	01997.013600.8	2374
45743	7590	06/28/2006	EXAMINER	
FITZPATRICK CELLA (WYETH) 30 ROCKEFELLER PLAZA NEW YORK, NY 10112-3800			HISSONG, BRUCE D	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 06/28/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/626,686	KATO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Bruce D. Hissong, Ph.D.	1646	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1,2,5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) 5 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### **Formal Matters**

1. Applicant's response to the Office Action mailed on 1/26/2006, including arguments and remarks, and amendments to the claims and specification, was received on 4/6/2006, and has been made of record.

2. The text of those sections of Title 35, U.S.C. not included in this action can be found cited in full, in the previous Office Action mailed on 1/26/2006.

3. The claim amendments received on 4/6/2006 cancelled claims 3-4 and amended claims 1-2 and 5-6. Therefore, claims 1-2 and 5-6 are currently pending. Claims 1-2 are the subject of this Office Action, and claims 5-6 are withdrawn as being drawn to non-elected subject matter.

### **Priority**

In the Office Action mailed on 1/26/2006, it was determined that the earliest effective filing date for the instant application is 6/3/1998, which is the filing date of PCT/JP98/02445, because no certified copy of foreign application JAPAN 9-144948 was present in the instant application. The response received on 4/6/2006, the Applicants state that a certified copy was filed with PCT/JP98/02445. A certified copy has been obtained by the Office, and has been placed in the file for parent application 09/455,258. However, said copy is not in English. Therefore, the priority date determination of 6/3/1998, as set forth on p. 4 of the Office Action mailed on 1/26/2006, is maintained. If Applicants submit a certified English translation of said foreign priority document, then the filing date will be reconsidered.

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**Specification**

**Objections withdrawn**

1. Objection to the specification for improper use of trademarks, as set forth on p. 4-5 of the Office Action mailed on 1/26/2006, is withdrawn in response to Applicant's amendments to the specification.

2. Objection to the title as not being descriptive of the invention, as set forth on p. 5 of the Office Action mailed on 1/26/2006, is withdrawn in response to Applicant's amendment to the title.

**Objections maintained**

3. The specification remains objected to for failing to include sequence identifiers, as set forth on p. 5 of the Office Action mailed on 1/26/2006.

**Claim Objections**

1. Objection to claim 1 for reciting non-elected subject matter, as set forth on p. 5 of the Office Action mailed on 1/26/2006, is withdrawn in response to Applicant's amendment to the claim to recite SEQ ID NO: 1.

**Claim Rejections - 35 USC § 101**

**Rejections withdrawn**

1. Rejection of claim 1 under 35 USC § 101, regarding non-statutory subject matter, as set forth on pages 5-6 of the prior Office Action mailed on 1/26/2006, is withdrawn in response to Applicant's amendment to the claim to read on "An isolated protein.....".

**Rejections maintained/necessitated by amendment**

2. Claim 1 remains rejected, and amended claim 2 is also rejected, under 35 USC § 101, as not being supported by a specific, substantial and credible asserted utility, or a well-established utility for the protein of SEQ ID NO: 1, as set forth on p. 6-8 of the Office Action mailed on 1/26/2006. In the response received on 4/6/2006, the Applicants argue that the

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instant specification teaches that the protein of SEQ ID NO: 1 is an alpha-2-HS-glycoprotein precursor protein, and that the teachings of Edwards *et al* (US 2004/0110939), cited in the 35 U.S.C. 102(e) rejection, further support this finding, and as such, the instant protein of SEQ ID NO: 1 would be expected to promote growth in tissue culture, enhance bone resorption, and stimulate adipogenesis. These arguments have been fully considered and are not found persuasive.

Edwards *et al* does not specifically teach a function for the protein of SEQ ID NO: 425, which is 100% identical to SEQ ID NO: 1 of the instant application (see sequence comparison mailed with the Office Action of 1/26/2006), but teaches that the protein of SEQ ID NO: 425 has homology to alpha-2-HS-glycoprotein precursors (see paragraph 0220). Furthermore, the specification of the instant application teaches that the protein of SEQ ID NO: 1 is a protein that has only 25% homology to alpha-2-HS-glycoproteins. Thus, the Applicants, and Edwards *et al*, have *putatively* identified the protein of their invention as an alpha-2-HS-glycoprotein precursor. However, neither Edwards *et al* nor the instant application disclose any specific biological role of the claimed protein of SEQ ID NO: 1 (or SEQ ID NO: 425 in Edwards *et al*) or its significance, and the basis that the protein of the present invention is an alpha-2-HS-glycoprotein precursor is not necessarily predictive of a use. The specification does not disclose any function or disease state associated with altered levels or forms of the protein of SEQ ID NO: 1. The Applicants have only based the function of the protein of the present invention on homology to other proteins. Therefore, because the specific function of this protein would be speculative and significant, further experimentation would be required of the skilled artisan to identify a dysfunction or disease that is associated with the protein of SEQ ID NO: 1. There is no disclosure, for example, of any symptoms associated with a disease or function of this polypeptide.

The specification discloses that the protein of SEQ ID NO: 1 has sequence similarity to known alpha-2-HS-glycoprotein family proteins. Based on the structural similarity, the specification asserts that the newly disclosed protein of SEQ ID NO: 1 has a similar activity. The assertion that the disclosed proteins have biological activities similar to known alpha-s-HS-glycoprotein family receptors cannot be accepted in the absence of supporting evidence, because generally, the art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases. For example, Skolnick *et al* (2000, *Trends in Biotech.* 18:34-39) state that knowing the protein structure by itself is

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insufficient to annotate a number of functional classes, and is also insufficient for annotating the specific details of protein function (see Box 2, p. 36). Similarly, Bork (2000, *Genome Research* 10:398-400) states that the error rate of functional annotations in the sequence database is considerable, making it even more difficult to infer correct function from a structural comparison of a new sequence with a sequence database (see especially p. 399). Such concerns are also echoed by Doerks *et al.* (1998, *Trends in Genetics* 14:248-250) who state that (1) functional information is only partially annotated in the database, ignoring multi functionality, resulting in underpredictions of functionality of a new protein and (2) overpredictions of functionality occur because structural similarity often does not necessarily coincide with functional similarity. Smith *et al.* (1997, *Nature Biotechnology* 15:1222-1223) remark that there are numerous cases in which proteins having very different functions share structural similarity due to evolution from a common ancestral gene.

Brenner (1999, *Trends in Genetics* 15:132-133) argues that accurate inference of function from homology must be a difficult problem since, assuming there are only about 1000 major gene superfamilies in nature, then most homologs must have different molecular and cellular functions. Finally, Bork *et al.* (1996, *Trends in Genetics* 12:425-427) add that the software robots that assign functions to new proteins often assign a function to a whole new protein based on structural similarity of a small domain of the new protein to a small domain of a known protein. Such questionable interpretations are written into the sequence database and are then considered facts.

Therefore, based on the discussions above concerning the specific examples of structurally similar proteins that have different functions, along with the art's recognition that one cannot rely upon structural similarity alone to determine functionality, the specification fails to teach the skilled artisan the utility of the protein of SEQ ID NO: 1, wherein said protein is only known to be homologous to alpha-2-HS-glycoprotein family proteins. Thus, the instant claims are drawn to a protein that has an undetermined function or biological significance. There is no actual and specific significance that can be attributed to the protein of SEQ ID NO: 1 identified in the specification. For this reason, the instant invention is incomplete. In the absence of knowledge of the biological significance of this protein, there is no immediately obvious patentable use for it. Because the instant specification does not disclose a "real-world" use for the protein of SEQ ID NO: 1, the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. 101 as being useful.

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The instant situation is directly analogous to that of which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anticancer activity was alleged to be potentially useful as an antitumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. 101, which required that an invention must have either an immediate obvious or fully disclosed "real-world" utility. The court held that:

"The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility," "[u]nless and until a process is refined and developed to this point - where specific benefit exists in currently available form - there is insufficient justification for permitting an applicant to engross what may prove to be a broad field," and "a patent is not a hunting license," "[i]t is not a reward for the search, but compensation for its successful conclusion."

There is little doubt that, after complete characterization, this protein will probably be found to have a patentable utility. This further characterization, however, is part of the act of invention and, until it has been undertaken, the Applicants' claimed invention is incomplete.

**Claim Rejections - 35 USC § 112, first paragraph - enablement**

Claim 1 remains rejected, and amended claim 2 is also rejected, under 35 USC § 112, first paragraph, as set forth on p. 8 of the Office Action mailed on 1/26/2006. The Applicants, in the reply received on 4/6/2006, argue that the protein of SEQ ID NO: 1 has utility by virtue of being a member of the alpha-2-HS-glycoprotein precursor family. This argument has been fully considered and is not persuasive. For the reasons set forth above in the 35 U.S.C. 101 utility rejection, claims 1 and 2 are not supported by a specific asserted utility or a substantial, well-established utility, and therefore one of ordinary skill in the art would not know how to make and use the claimed invention.

**Claim Rejections - 35 USC § 102**

Claim 1 remains rejected, and amended claim 2 is also rejected, under 35 USC § 102(e), as being anticipated by Edwards *et al* (US 2004/0110939), as set forth on p. 9 of the Office Action mailed on 1/26/2006. In the response received on 4/6/2006, the Applicants argue that due to priority to JAPAN 9-1144948, the earliest effective filing date of the instant application is 6/3/1997, and therefore Edwards *et al*, which ultimately claims priority to US provisional application 60/066,677, filed 11/3/1997, is not proper prior art under 35 U.S.C. 102(e). However, in light of the determination of the priority date as set forth above, the rejection is maintained for the reasons set forth on p. 9 of the Office Action mailed on 1/26/2006.

**Conclusion**

No claim is allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

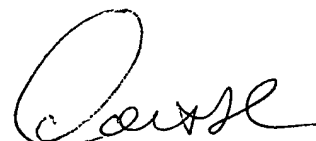
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D., whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, Ph.D. can be reached at (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BDH  
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ROBERT S. LANDSMAN, PH.D.  
PRIMARY EXAMINER